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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,368	12/21/2001	Catherine C. Thompson	P 0283266	3991
909	7590	03/01/2004	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			CARLSON, KAREN C	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,368	THOMPSON	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 19-21, drawn to polypeptide, classified in class 530, subclass 350.
- II. Claims 1-18, drawn to polynucleotide encoding SEQ ID NO: 2, classified in class 536, subclass 23.1.
- III. Claims 22 and 23, drawn to method of screening for a chemical agent that modulates Hairless-mediated transcription in vivo, classified in class 453, subclass 6.
- IV. Claims 22 and 24, drawn to method of screening for a chemical agent that modulates Hairless-mediated transcription in vivo, classified in class 435, subclass 6.

Claim 22 is presented in both Inventions III and IV. If either Invention III or IV is elected, Claim 22 will be examined only in-so-far as it pertains to the elected subject matter.

- V. Claims 25-27, drawn to method of screening for a chemical agent that modulates Hairless and thyroid receptor binding, classified in class 435, subclass 7.1.
- VI. Claims 28 and 32, drawn to method of screening for a chemical agent that modulates Hairless polynucleotide expression, classified in class 435, subclass 6.
- VII. Claims 28, 30, 31, and 33, drawn to method of screening for a chemical agent that modulates Hairless polypeptide activity, classified in class 435, subclass 7.1.
- VIII. Claims 28 and 29, drawn to method of screening for a chemical agent that modulates Hairless gene expression in vivo, classified in class 435, subclass 6.
- IX. Claims 28 and 29, drawn to method of screening for a chemical agent that modulates Hairless polypeptide activity in vivo, classified in class 43, subclass 7.1.

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Claim 28 is presented in Inventions VI through IX. If either Invention VI through IX or IV is elected, Claim 28 will be examined only in-so-far as it pertains to the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions I and Inventions III, IV, V, VII, and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of the methods of Inventions III, IV, V, VII, or IX, or to make antibodies, for example.

Inventions II and Inventions VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a

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materially different process such as in any one of the methods of Inventions VI or VIII, or in the recombinant production of protein, for example.

The product of Invention I is not used in the method of Inventions VI or VIII. Therefore, Invention I is patentably distinct from Inventions VI and VIII.

The product of Invention II is not used in the method of Inventions III, IV, V, VII, or IX. Therefore, Invention II is patentably distinct from Inventions III, IV, V, VII, and IX.

The methods of Inventions III, IV, V, VII, and IX are related in that each method requires the use of the product of Invention I. However, the steps and end points of the methods are wholly different and therefore Inventions III, IV, V, VII, and IX are patentably distinct.

The methods of Inventions VI and VIII are related in that each method requires the use of the product of Invention II. However, the steps and end points of the methods are wholly different and therefore Inventions VI and VIII are patentably distinct.

The methods of Inventions III, IV, V, VII, and IX require different products and steps and have different endpoints than Inventions VI and VIII. Therefore, Inventions III through IX are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

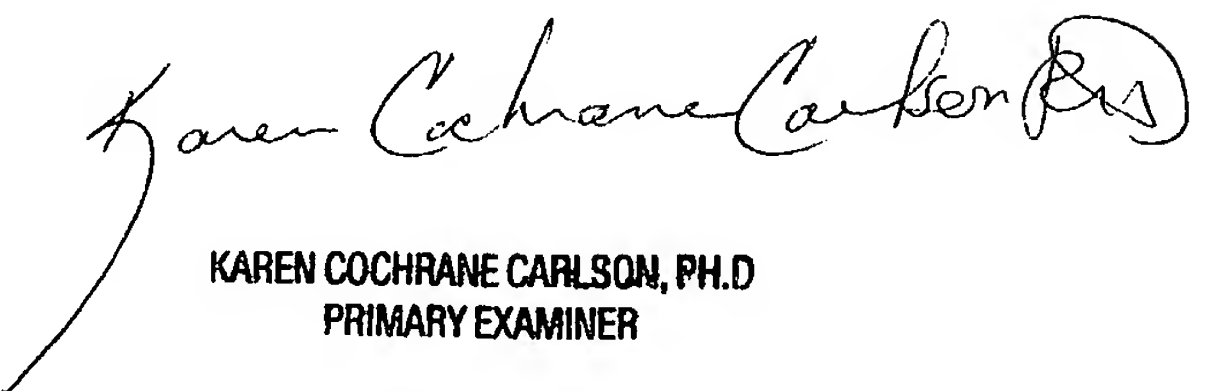
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER